

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Carl D. Wahlstrand, Confirmation No. 6690
Ruchika Singhal and
Robert M. Skime
Serial No.: 10/731,869
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Examiner: Alyssa M. Alter
Group Art Unit: 3762
Docket No.: 1023-318US01
Title: MODULAR IMPLANTABLE MEDICAL DEVICE

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on April 17, 2009.

By: 

Name: Patricia Cygan

RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

Please find below a replacement section for the "ARGUMENT" section of the Appeal Brief filed on February 19, 2009 for this application. This replacement section is responsive to the Notice of Non-Compliant Appeal Brief mailed March 19, 2009, the period of response for which runs through April 19, 2009. The Notice indicated that the Appeal Brief was defective because it did not present an argument under a separate heading for each ground of rejection. The Notice indicated that an entire replacement Appeal Brief was not required, and that only the section found defective, i.e., the "ARGUMENT" section, was required.

No fee is believed to be due with this submission. Please charge any fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

ARGUMENT

Appellant respectfully traverses the current rejections of claims 1–31 and 33–61 advanced in the final Office Action dated June 20, 2008, and requests reversal by the Board of Patent Appeals based on the arguments below. For each ground of rejection, Appellant respectfully requests separate review of each set of claims argued under separate headings. For at least the reasons presented below, the Examiner has failed to establish a *prima facie* case of anticipation with respect to Appellant’s claims 1–4, 6–9, 11–25, 27–30, 33–49, 51–56, and 58–61. In addition, for at least the reasons presented below, the Examiner has failed to establish a *prima facie* case of obviousness with respect to Appellant’s claims 5, 10, 26, 31, 50, 55, and 57. As noted below, the provisional rejection of claims 1–31 and 33–61 under the judicially created doctrine of obviousness-type double patenting has been rendered moot by the filing of a Terminal Disclaimer.

For at least these reasons, Appellant respectfully requests reversal of the rejections of claims 1–31 and 33–61.

FIRST GROUND OF REJECTION UNDER APPEAL- THE REJECTION OF CLAIMS 1–4, 6–9, 11–25, 27–30, 33–49, 51–54, 56, AND 58–61 UNDER 35 U.S.C. § 102(E) AS BEING ANTICIPATED BY BERRANG

Claims 1–4, 6–9, 11–25, 27–30, 33–49, 51–54, 56, and 58–61 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Berrang.

CLAIMS 1–4, 12, 13, 16–18, 20–25, 33, 35, 37–38, 42–44, 51, and 53–55

Berrang fails to teach or suggest an implantable medical device comprising a first module that includes control electronics within a first housing, a second module that includes a second housing, and an overmold that at least partially encapsulates the first and second housings, where the first and second housings are coupled, and the coupling of the first and second housings allows the housings to have a plurality of degrees of freedom of movement relative to each other, as recited by Appellant’s independent claim 1.

In support of the rejection of independent claim 1, the Examiner stated that “Berrang et al. discloses a first and second modules [sic] disposed within corresponding first and second housing [sic] in addition to the pliable (or bendable) bridge, which the examiner considers to be

an overmold” and referenced FIG. 1 of Berrang.¹ The Examiner characterized housing sections 2 and 3, which are also shown in FIGS. 2 and 3 of Berrang, as modules that have respective housings encapsulated by an overmold.² Appellant respectfully disagrees with the Examiner’s characterization of the housing sections 2, 3 of Berrang as first and second modules that each comprises a housing, as required by Appellant’s claim 1, and the characterization of the bridge 6 as an overmold that at least partially encapsulates housings of the housing sections 2, 3.

Berrang clearly and repeatedly describes its device as having a single housing (“the housing”) comprising two sections.³ For example, in the Summary of the Invention provided in Berrang, Berrang states that its implanted part comprises: (a) a housing, (b) a coil, (c) a microphone, and (d) an electrode array.⁴ At no time does Berrang teach or even suggest that its device includes at least a first module comprising a first housing and a second module comprising a second housing, much less an overmold that at least partially encapsulates the first and second housings, as recited by Appellant’s independent claim 1.

The Examiner reasoned that because Berrang discloses that the housing of its device includes two sections, Berrang discloses first and second housings.⁵ This assertion overlooks the fact that Berrang only discloses a device comprising a single housing that contains the electronics, battery, and so forth.⁶ The housing sections 2, 3 disclosed by Berrang are merely two different regions of the housing. Berrang in no way suggests that each of the housing sections 2, 3 each comprise a respective housing. Berrang fails to recognize that distributing components of an implantable medical device into separate modules comprising respective housings, as required by Appellant’s claim 1, helps define a medical device that may be implanted at locations within the human body for which implantation of conventional implantable medical devices is deemed undesirable.⁷

The Examiner failed to provide any support for an assertion that the housing sections 2, 3 necessarily comprise respective housings. Given the lack of discussion in Berrang of a device comprising two housings and the explicit disclosure by Berrang of a device having a single housing, the Examiner appears to be relying on an improper finding of an inherent disclosure to

¹ Final Office Action dated June 20, 2008 at page 6, item 1.

² Final Office Action dated June 20, 2008 at page 6, item 1.

³ Berrang, at column 3, l. 25 – column 4, l. 4 and column 9, lines 51–62.

⁴ Berrang at column 2, lines 47–53.

⁵ Final Office Action dated June 20, 2008 at page 2.

⁶ Berrang at column 3, lines 26–30.

⁷ Appellant’s disclosure at page 6, lines 18–22.

support the assertion that the housing sections 2, 3 comprise respective housings. The fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that result or characteristic.⁸ The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.⁹ No reasonable support has been provided for the Examiner's assertion that housing sections 2, 3 necessarily comprise respective housings. Indeed, the allegedly inherent characteristic does not necessarily flow from the teachings of Berrang.

While the Examiner discussed the elements of Berrang that it considers to be first and second modules, the Examiner failed to provide an indication of the elements of the Berrang device that the Examiner considers to be the actual housings of the modules. Claim 1 requires the modules to have respective housings. Berrang fails to teach or even suggest that the housing sections 2, 3 include separate housings. Although at column 11, lines 60–63, Berrang discloses the use of a medical grade epoxy (or any biocompatible polymer) 28 to coat and encapsulate the internal components (mounted on the ceramic substrates 24 and 25) of the housing sections 2, 3, the epoxy does not define a housing for each the housing sections 2, 3. Berrang explicitly states that the outside edges of the ceramic substrates 24 and 25, or the areas over the snap domes 20 and 23 are not coated by the epoxy.¹⁰ Thus, the epoxy surfaces are not housings for elements 2 and 3, because the epoxy surfaces in no way house elements 2 and 3 as required by a housing. Rather, the epoxy surfaces are merely components of elements 2 and 3. The housing sections 2 and 3 of Berrang share a housing (i.e., the gold layer), and in no way have respective first and second housings, as required by Appellant's independent claim 1.

Furthermore, the bridge 6 of the Berrang device is not an overmold as asserted by the Examiner. Berrang discloses that the housing sections 2, 3 are connected by a bridge 6, which comprises a pliable metal.¹¹ Berrang does not contemplate an arrangement in which the bridge 6 at least partially encapsulates first and second housings of first and second modules, respectively, as required by Appellant's claim 1. In the Response to Arguments section provided in the final Office Action dated June 20, 2008, the Examiner asserted that FIGS. 2 and 4 of Berrang

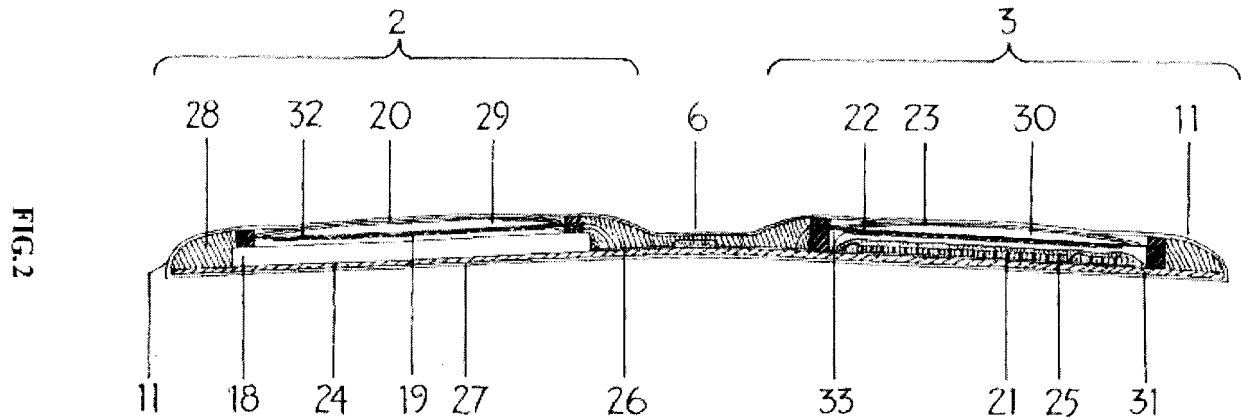
⁸ *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ.2d 1955, 1957 (Fed. Cir. 1993); MPEP § 2112.

⁹ *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112.

¹⁰ Berrang at column 11, lines 60–63.

¹¹ Berrang at column 9, lines 51–54.

illustrate a bridge 6 that at least partially encapsulates two housing sections 2, 3.¹² Appellant respectfully disagrees. Even if the housing sections 2, 3 are modules, an assertion with which Appellant disagrees, FIGS. 2 and 4 do not illustrate a bridge 6 that at least partially encapsulates housings of the housing sections 2, 3. FIGS. 2 (reproduced below) and 4 of Berrang appear to illustrate a bridge structure 6 that is merely adjacent to housing sections 2, 3.



Nothing shown within FIGS. 2 and 4 or disclosed within the Berrang detailed description suggests that the bridge 6 at least partially encapsulates housings of the housing sections 2, 3. Instead, the bridge 6 appears to merely be a component that is placed between the housing sections 2, 3. Berrang even describes the bridge 6 as being a “connecting bridge between said sections.”¹³

For the reasons discussed above with respect to Appellant’s independent claim 1, Berrang fails to teach or suggest an implantable medical device comprising a first module that includes control electronics housed within a first housing, a second module that includes a power source that provides power to the first module housed within a second housing, an interconnect member that flexibly couples the first and second housings, where the interconnect member is flexible in a plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other, and a flexible overmold that at least partially encapsulates the first and second housings, as recited by Appellant’s independent claim 23.

Appellant’s independent claim 42 is directed toward an implantable medical device that comprises a first module comprising control electronics and a therapy delivery circuit housed within a first housing, a second module comprising a power source within a second housing, an

¹² Final Office Action dated June 20, 2008 at page 2.

¹³ Berrang at column 8, lines 17–19 (emphasis added).

interconnect member that flexibly couples the first and second modules and includes a conductor for delivery power from the power source to the control electronics and the therapy delivery circuit, and a flexible overmold that at least partially encapsulates the first and second housings. As discussed above with respect to independent claim 1, Berrang fails to teach or suggest at least first and second modules each comprising a respective housing, as well as an overmold that at least partially encapsulates the first and second housings. For at least these reasons, Appellant's independent claim 42 is patentable over Berrang.

Claims 2–4, 12, 13, 16–18, 20–22 depend from independent claim 1, claims 24, 25, 33, 35, 37, and 38 depend from independent claim 23, claims 43, 44, 51, 53–55 depend from independent claim 42. For at least the reasons discussed above with respect to independent claim 1, 23, 39, and 42, the dependent claims are patentable over Berrang, and the rejection of the dependent claims should be reversed.

CLAIMS 6, 27, AND 46

Claims 6 and 27 specify that the implantable medical devices of claims 1 and 23 each include a third module that includes a third housing that houses a recharge coil. The Examiner asserted that FIG. 1 of Berrang illustrates a housing that houses the coil 4, and, therefore, Berrang anticipates claims 6 and 27.¹⁴ Appellant respectfully disagrees. Berrang does not disclose or suggest that the coil 4 is housed in a housing, and FIG. 1 does not illustrate a housing.

CLAIM 7–10, 28–31, AND 47–50

Claims 7, 28, and 47 each specify that the third module of claims 6, 27, and 46, respectively, that includes a recharge coil, is at least partially encapsulated by the overmold that also at least partially encapsulates the first and second modules of the implantable medical device. The Examiner failed to establish a *prima facie* case of anticipation of claims 7, 28, and 47. For example, the Examiner failed to demonstrate how Berrang discloses or suggests an implantable medical device that includes an overmold that at least partially encapsulates first, second, and third modules, where the third module includes a housing that houses a recharge coil, as required by Appellant's claims 7, 28, and 47. As indicated above, the Examiner

¹⁴ Final Office Action dated June 20, 2008 at page 6, item 1.

characterized the bridge 6 of the Berrang device as an overmold.¹⁵ Berrang does not disclose or even suggest that the bridge 6 at least partially encapsulates the coil 4, as apparently asserted by the Examiner.

As shown in FIG. 1 of Berrang, the bridge 6 appears to be adjacent to the coil 4, rather than at least partially encapsulating the coil 4. Moreover, the arrangement of the bridge 6 relative to the coil 4 does not permit the bridge 6 to even contact the coil 4. Berrang states that the bridge 6 and housing sections 2, 3 are coated in gold. It is unclear how the bridge 6 at least partially encapsulates the housing sections 2, 3, as well as the coil 4, which is located outside of the gold coating.

CLAIMS 9, 30, AND 49

Claims 9, 30, and 49 each specify that the third module of claims 6, 27, and 46, respectively, is located outside of the overmold and a flexible tether member connects the third module to the overmold. Not only does Berrang fail to disclose that the coil 4 comprises a housing, but Berrang also fails to disclose an arrangement in which the coil 4 is located outside of an overmold and connected to the overmold via a flexible tether member.

The Examiner rejected claims 7, 28, and 47, as well as claims 9, 30, and 49 as being anticipated by Berrang. It is unclear how the coil 4 disclosed by Berrang can be at least partially encapsulated by an overmold (the bridge 6 of the Berrang device according to the Examiner), as recited by claims 7, 28, and 47, and located outside of the overmold, as recited by claims 9, 30, and 49, as the Examiner suggested. In the final Office Action, the Examiner stated that in the example of the device shown in FIG. 1, the coil 4 is located in the bridge 6 (which the Examiner characterized as an overmold), and in the example shown in FIGS. 15 and 16 of Berrang, the coil 4 is located outside of the bridge 6 and connected to the bridge 6 via a flexible tether member.¹⁶ Berrang offers absolutely no support for the Examiner's assertion that FIGS. 1, 15, and 16 illustrate different positions of the coil 4 with respect to the bridge 6.

To the extent Berrang describes FIGS. 15 and 16, Berrang states that FIGS. 15 and 16 "illustrate alternate embodiments . . . showing the coil 4 and the two housing sections."¹⁷ Berrang states that FIG. 15 illustrates a configuration of a coil and two housing sections, where

¹⁵ Final Office Action date June 20, 2008 at page 6, item 1.

¹⁶ Final Office Action dated June 20, 2008 at pages 6 and 7, item 1.

¹⁷ Berrang at column 15, l. 66 – column 16, l. 2.

the coil is inferior, and FIG. 16 illustrates a configuration in which the coil is anterior.¹⁸ The inferior and anterior locations of the coil 4 have nothing to do with the position of the coil relative to the bridge 6. In addition, Berrang does not state that the coil 4 is connected to the bridge 6 in a different manner in FIGS. 15 and 16 as compared to the examples shown in the other figures, such as FIG. 1. Thus, contrary to the Examiner's assertions, Berrang does not disclose both an implantable medical device in which a recharge coil is within an overmold and an implantable medical device in which a recharge coil is located outside an overmold and is connected to the overmold via a flexible tether member.

The Examiner has failed to demonstrate that Berrang discloses that the coil 4 is both at least partially encapsulated by an overmold and located outside of an overmold. Claim 8 depends from claim 7, claim 10 depends from claim 9, claim 29 depends from claim 28, claim 31 depends from claim 30, claim 48 depends from claim 47, and claim 50 depends from claim 49. For at least these reasons, the rejection of claims 7–10, 28–31, and 47–50 should be reversed because the Examiner has failed to establish a *prima facie* case of anticipation with respect to claims 7–10, 28–31, and 47–50.

CLAIM 11

Claim 11 specifies that the overmold of claim 1 completely encapsulates the first and second modules. Berrang fails to disclose or suggest an overmold that completely encapsulates the first and second modules. The Examiner characterized the bridge 6 of the Berrang device as an overmold and stated that the bridge 6 “partially encapsulates the . . . first and second housing [sic].”¹⁹ Claim 11, on the other hand, requires an overmold that completely encapsulates first and second modules. The Examiner failed to address this requirement of claim 11. As provided in 37 C.F.R. 1.104(c)(2), the Examiner must designate the particular part of a reference as nearly as practicable. However, with respect to claim 11, as well as many of the other dependent claims, the Examiner has failed to do so. Thus, on at least the basis that the Examiner failed to meet the burden of demonstrating that Berrang discloses every element of claim 11, Appellant respectfully requests reversal of the rejection of claim 11.

¹⁸ Berrang at column 9, lines 20–25.

¹⁹ Final Office Action dated June 20, 2008 at page 6, item 1 (emphasis added).

CLAIM 14

Claim 14 specifies that the overmold of claim 1 comprises silicone. In support of the rejection of claim 14, the Examiner stated that because Berrang discloses that the housing sections 2, 3 and the bridge structure 6 “are preferentially coated with gold, and, in a further embodiment, further coated with titanium, platinum, medical grade silicone, or any combination thereof,” Berrang discloses an overmold that comprises silicone.²⁰ Appellant respectfully disagrees that the silicone disclosed by Berrang is a part of an overmold in accordance with Appellant’s claim 14.

As discussed above, the Examiner characterized the bridge structure 6 in the Berrang reference as an overmold. Berrang explicitly states that the bridge structure 6 contains a pliable metal, such as gold or platinum.²¹ Berrang does not contemplate any other materials for the bridge structure 6. The silicone is not part of the Berrang bridge structure 6. While Berrang states that the bridge structure 6 may be coated with silicone, Berrang does not disclose that the silicone itself is not part of the bridge structure 6. Instead, the silicone is merely coated over the Berrang implanted device, which happens to include the bridge structure 6.

CLAIM 15

Claim 15 specifies that the overmold of claim 1 comprises at least two materials. In support of the rejection of claim 15 as being anticipated by Berrang, the Examiner characterized the bridge structure 6 and a gold coating disclosed by Berrang as an overmold comprising at least two materials. The Examiner stated that column 9, lines 58–62 of Berrang discloses that “the housing sections 2 and 3 and bridge structure 6 are preferentially coated with gold, and, in a further embodiment, further coated with titanium, platinum, medical grade silicone, or any combination thereof.”²² In the final Office Action, the Examiner also clarified that the Examiner does not consider the gold to be the overmold itself, but to be “merely incorporated into the overmold.”²³

Appellant respectfully disagrees that the gold coating the bridge structure 6 is “incorporated” into the bridge structure 6. Berrang does not provide any support for the

²⁰ Final Office Action dated June 20, 2008 at page 7, item 1.

²¹ Berrang at column 9, lines 52–53.

²² Final Office Action dated June 20, 2008 at page 6, item 1.

²³ Final Office Action dated June 20, 2008 at page 2.

assertion that the gold coating is incorporated into the bridge structure 6. Instead, Berrang merely states that the bridge structure, as well as the housing sections 2, 3 are coated with the gold. Thus, the gold and bridge structure 6 appear to be separate components of the Berrang device and the gold cannot reasonably be characterized as being “incorporated” into the bridge structure 6 such that the bridge structure comprises at least two materials, as asserted by the Examiner.

CLAIMS 19, 36, AND 52

Claims 19, 36, and 52 each specify that the implantable medical device of claim 1, 23, and 42, respectively, further comprises a lead connection module formed within the overmold to receive one of a lead that includes an electrode and a lead extension that is coupled to the lead, and a conductor that extends from the lead connection module to the first module, where the first housing comprises a hermetic feedthrough to receive the conductor and the conductor electrically couples the electrode to the first module. The Examiner rejected claims 19, 36, and 52 as being anticipated by Berrang. However, Berrang fails to disclose, among other things, a first housing that comprises a hermetic feedthrough. The Examiner asserted that the Berrang device includes a lead connection module “between the bridge 6 and the lead junction 16.” Even if this is true, an assertion with which Appellant disagrees, Berrang fails to disclose that the housing section 3 (the “first module” according to the Examiner²⁴) includes a hermetic feedthrough that receives a conductor.

Berrang discloses that the internal components of the housing section 3 are mounted to a ceramic substrate 25, which contains a plurality of electrically insulated electrical lead-throughs.²⁵ Even if the lead-throughs disclosed by Berrang are feedthroughs that receive a conductor, Berrang fails to disclose that the lead-throughs are hermetic. Moreover, it does not necessarily follow from the Berrang disclosure that the lead-throughs are inherently hermetic. Accordingly, Berrang fails to disclose or suggest each and every element of claims 19, 36, and 52.

The housing section 3 of the Berrang device is not hermetically sealed. Thus, it is unclear why the electrical lead-throughs of the ceramic substrate 25 of the Berrang device would

²⁴ Final Office Action dated June 20, 2008 at page 6, item 1.

²⁵ Berrang at column 11, lines 45–48.

be hermetic. According to Berrang, the components on the ceramic substrate 25 of the housing section 3 are covered with an epoxy, which does not provide a true hermetic seal.²⁶ Accordingly, the housing sections 2, 3 are covered with a common layer of gold to achieve a hermetic seal. The lead-throughs of the ceramic substrate 25 are enclosed within the layer of gold, and, thus, hermetic feed-throughs in the ceramic substrate 25 are not necessary to maintain the hermetic seal of the Berrang device.

CLAIMS 34 AND 39–41

Berrang fails to teach or suggest each and every element of Appellant’s independent claim 39 and claim 34. Claim 39 recites an implantable medical device that comprises a first module that includes control electronics housed within a first housing, a second module that includes a power source that provides power to the first module housed within a second housing, and a hermetic interconnect member that flexibly couples the first and second housings, where the interconnect member is flexible in a plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other. Claim 34 states that the interconnect member of the medical device of independent claim 23 is hermetic and defines at least one lumen between the housings of the first and second modules.

As discussed above with respect to independent claim 1, Berrang fails to disclose or suggest the first and second modules comprising respective housings. In addition, Berrang fails to teach or suggest a hermetic interconnect member, as required by claims 34 and 39.

The Examiner asserted that “the pliable bridge unites the two housings and as a result acts as a hermetic interconnect member.”²⁷ Appellant respectfully disagrees. Berrang fails to disclose or even suggest that the bridge structure 6 is hermetic. The Examiner offered absolutely no support for this assertion. For example, the Examiner failed to describe or point to a lumen in the bridge 6 of the Berrang device, which the Examiner characterized as a “interconnect member.” Berrang fails to disclose or suggest that the bridge 6 includes a lumen between the housings of the first and second housing sections 2, 3, which the Examiner characterized as “modules.” Berrang discloses that the bridge structure 6 comprises a pliable metal. As shown in FIG. 2 of Berrang (reproduced above), the bridge 6 does not appear to define a lumen that

²⁶ Berrang at column 3, lines 59–61 and column 11, lines 55–63.

²⁷ Final Office Action dated June 20, 2008 at page 2.

extends between the housing sections 2, 3, and, instead, appears to comprise a solid structure. Berrang also fails to disclose or suggest that the bridge 6 is hermetic.

The rejection to claims 34 and 39 should be reversed because the Examiner failed to meet the burden of demonstrating that Berrang discloses each and every element of claims 34 and 39 and because Berrang fails to disclose each and every element of claims 34 and 39. Claims 40 and 41 depend from independent claim 39 and are patentable over Berrang for at least the same reasons discussed with respect to claim 39.

CLAIM 45

Claim 45 specifies that the implantable medical device of independent claim 42 includes a recharge coil located within the overmold, where the recharge coil substantially encircles the first and second modules. The Examiner rejected claim 45 as being anticipated by Berrang. However, with respect to the rejection of claims 5 and 26, the Examiner acknowledged that Berrang fails to disclose or suggest a recharge coil that substantially encircles the first and second modules of an implantable medical device.²⁸ As discussed in further detail below, the Examiner asserted that claims 5 and 26 would have been obvious in view of Berrang.

The Examiner characterized the coil 4 of the Berrang device as a recharge coil, the bridge 6 as an overmold, and housing sections 2, 3 as modules. Berrang fails to disclose or suggest that the coil 4 is within the bridge 6, and, thus, the Berrang fails to disclose or suggest a recharge coil located within the overmold, as required by Appellant's claim 45. Moreover, the Examiner acknowledged that Berrang fails to disclose that the coil 4 substantially encircles the first and second housing sections 2, 3. Thus, even if the housing sections 2, 3 are modules, an assertion with which Appellant disagrees, Berrang fails to disclose or suggest the arrangement between a recharge coil and modules disclosed by Appellant's claim 45. For at least these reasons, the rejection of claim 45 as being anticipated by Berrang should be reversed.

As discussed with respect to claims 5 and 26 below, it would not have been obvious to one having ordinary skill in the art to modify Berrang such that the coil 4 is within the bridge 6 and substantially encircles the housing sections 2, 3. Thus, claim 45 is novel and nonobvious over Berrang.

²⁸ Final Office Action dated June 20, 2008 at page 8, item 2.

CLAIM 56

Berrang also fails to teach or suggest each and every element of Appellant's independent claim 56. Claim 56 is directed to an implantable medical device that comprises a first module comprising control electronics within a first housing, a second module comprising a recharge coil within a second housing, a third module comprising a rechargeable power source within a third housing, an overmold that at least partially encapsulates the first and third housings, and a flexible tether member that connects the overmold and the second housing. Berrang does not teach or suggest such elements, much less an arrangement in which control electronics and a rechargeable power source are provided in separate housings that are at least partially encapsulated by an overmold, and a recharge coil is provided within another housing that is connected to the overmold. Furthermore, the Examiner failed to meet the burden of demonstrating that Berrang anticipates such an arrangement of the control electronics, rechargeable power source, and recharge coil.

As discussed above with respect to dependent claims 9, 30, and 49, which each specify that a third module is located outside of an overmold and connected to the overmold via a flexible tether member, the Examiner has failed to support the assertions that Berrang discloses both an implantable medical device in which a module including a recharge coil is located outside of an overmold and an implantable medical device in which the module including the recharge coil is at least partially encapsulated by an overmold (e.g., as recited in claims 7, 28, and 47). Accordingly, the rejection of independent claim 56 and the claims dependent therefrom should be reversed.

CLAIMS 58–61

Claims 58–61 each specify that at least one of the housings of the modules of a medical device comprises a hermetic housing. As an initial matter, Appellant notes that the Examiner failed to specifically address the features of Appellant's claims 58–61 and failed to provide any explanation of how Berrang discloses each and every element of claims 58–61. While claims 58–61 were rejected as being anticipated by Berrang, the Examiner failed to provide any explanation of how Berrang discloses the requirements of claims 58–61. Indeed, the final Office Action fails to make any mention of medical device modules comprising hermetic housings.

Berrang fails to disclose or suggest the requirements of claims 58–61. The Examiner reasoned that housing sections 2 and 3 of the Berrang device were modules. However, the sections 2 and 3 do not have separate housings, and Berrang specifically states that the epoxy that is used to coat and encapsulate the internal components of elements 2 and 3 do “not provide a true hermetic or hermetic like seal.”²⁹ For this reason, Berrang provides a single gold coating over the encapsulant surface.³⁰ Thus, Berrang does not disclose or suggest a device including at least two modules comprising separate housings, where at least one of the housings comprises a hermetic housing, as recited by Appellant’s claims 58–61.

For at least these reasons, the rejection of claims 1–4, 6–9, 11–25, 27–30, 33–49, 51–54, 56, and 58–61 was improper and should be reversed.

SECOND GROUND OF REJECTION UNDER APPEAL – THE REJECTION OF CLAIM 55 UNDER 35 U.S.C. § 102(E), OR, IN THE ALTERNATIVE, UNDER 35 U.S.C. § 103(A) IN VIEW OF BERRANG

Claim 55 specifies that the therapy delivery circuit of independent claim 42 comprises a pulse generator. Claim 55 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Berrang, or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Berrang. In particular, the Examiner stated that the Berrang device necessarily includes a pulse generator, or, in the alternative, it would have been obvious to modify Berrang to include a pulse generator.³¹ As discussed above, Berrang fails to disclose or suggest each and every element of independent claim 42. Accordingly, claim 55, which includes all of the limitations of claim 42, is novel over Berrang.

THIRD GROUND OF REJECTION UNDER APPEAL – THE REJECTION OF CLAIMS 5, 10, 26, 31, 50, AND 57 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER BERRANG

Claims 5, 10, 26, 31, 50, and 57 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang.

²⁹ Berrang at column 3, lines 59–65.

³⁰ Berrang at column 3, lines 59–65.

³¹ Final Office Action dated June 20, 2008 at page 8, item 1.

CLAIMS 5 AND 26

Claims 5 and 26 specify that the implantable medical devices of claims 1 and 23, respectively, each include a recharge coil located within the overmold, where the recharge coil substantially encircles the first and second modules. In support of the rejection of claims 5 and 26, the Examiner acknowledged that Berrang fails to disclose or suggest the recharge coil of claim 5, but asserted that claim 5 would have been obvious in view of Berrang because “it has been held that rearranging parts of an invention involves only routine skill in the art.”³² Appellant respectfully disagrees with this conclusion of obviousness.

Berrang discloses a coil 4 that may be used to recharge a battery 18 housed within a housing section 2 of its device.³³ As shown in FIG. 1 of Berrang, the coil 4 does not substantially encircle the housing sections 2, 3, which the Examiner characterized as modules. Modification of the Berrang device to position the coil 4 around the housing sections 2, 3 requires more than just a rearrangement of parts. For example, as shown in FIG. 1, the coil 4 has a smaller diameter than the perimeter substantially encircling the housing sections 2, 3. Thus, the modification proposed by the Examiner would require changing the shape and size of the coil 4. Berrang does not provide any suggestion that such a modification to the coil 4 would be useful or that, so modified, the coil 4 would still be useful for its intended purpose. For example, modifying the size and shape of the coil 4 may change the principal of operation of the recharge coil.

Moreover, Berrang discloses that an “inventive feature” of its device is the location of the coil 4 away from interfering metal materials, which, according to Berrang, improves the inductive power coupling efficiency across a skin surface with an external coil.³⁴ Berrang provides absolutely no basis for concluding that positioning the coil 4 such that it substantially encircles the housing sections 2, 3 would maintain this feature of the Berrang disclosure. Accordingly, modifying the Berrang device such that the coil 4 is sized to substantially encircle the housing sections 2, 3, as suggested by the Examiner, would not have been obvious in view of the Berrang disclosure. Indeed, one having ordinary skill in the art would have consciously avoided such a modification to Berrang in view of the explicit inventive feature of the device to locate the coil 4 away from interfering metal materials.

³² Final Office Action dated June 20, 2008 at page 8, item 2.

³³ Berrang at column 12, lines 50–54.

³⁴ Berrang at column 10, lines 35–39.

Absent access to Appellant's disclosure, there is no apparent reason why one having ordinary skill in the art would have modified Berrang in the manner proposed by the Examiner. The Examiner failed to identify a motivation or a rational reason why a person skilled in the art would have modified the Berrang device to substantially encircle the housing sections 2, 3 with the coil 4. The only reason provided by the Examiner for modifying Berrang was that "rearranging parts of an invention involves only routine skill in the art." However, it is established that "[t]he mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims . . . is not by itself sufficient to support a finding of obviousness."³⁵ The prior art must provide a motivation or a reason for the modification. Thus, the Examiner has failed to establish a *prima facie* case of obviousness with respect to claims 5 and 26.

For at least these reasons, claims 5 and 26 are nonobvious and patentable over Berrang, and the rejection of claims 5 and 26 should be reversed.

CLAIMS 10, 31, 50, AND 57

Claims 10, 31, 50, and 57 specify that the flexible tether member of claims 9, 30, 49, and 56, respectively, which connects a module including a recharge coil to an overmold, comprises a helix. Claims 10, 31, 50, and 57 are patentable over Berrang for at least the reasons discussed above with respect to the independent claims from which claims 10, 31, 50, and 57 depend. Moreover, claims 10, 31, 50, and 57 recite additional features that are neither disclosed nor suggested by Berrang.

In support of the rejection of claims 10, 31, 50, and 57, the Examiner stated that it would have been obvious to one having ordinary skill in the art "to modify the lead as taught by Berrang et al. with a helix shaped lead since it was known in the art that helix shaped leads reduce the slack in the lead."³⁶ This statement in support of the rejection, however, overlooks the fact that Berrang fails to disclose or suggest that the coil 4 (the module including a recharge coil according to the Examiner) is not connected to the bridge 6 (the "overmold" according to the Examiner) with a lead.

³⁵ MPEP 2144.04(VI)(C).

³⁶ Final Office Action dated June 20, 2008 at pages 8 and 9, item 2.

Thus, even if helix shaped leads were known in the art, an assertion with which Appellant does not necessarily agree, the Examiner has failed to establish a reason why one having ordinary skill in the art would have modified Berrang to include a flexible tether member comprising a helix. In addition to failing to state that the coil 4 is connected to the bridge 6 with a lead, Berrang fails to disclose that a connection between the coil 4 and the bridge 6 is affected by undue tension, such that a lead with reduced slack is desirable. Berrang is concerned with a coil 4 that has a thin profile.³⁷ Berrang does not provide any indication that a flexible tether comprising a tether would maintain the low profile of the coil 4. For at least these reasons, the conclusion of obviousness advanced by the Examiner is not supported by Berrang, and the rejection of claims 10, 31, 50, and 57 should be reversed.

FOURTH GROUND OF REJECTION UNDER APPEAL – THE PROVISIONAL REJECTION OF CLAIMS 1–31 AND 33–61 UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 1–31 and 33–61 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–23 of copending Application No. 10/731,638 (now U.S. Patent No. 7,212,864), claims 1–14 of copending Application No. 10/730,878 (U.S. Publication No. 2004/0176816), claims 1–23 of copending Application No. 10/731,699 (U.S. Publication No. 2004/0172090), claims 1–54 of copending Application No. 10/730,873 (now U.S. Patent No. 7,242,982), claims 1–27 of copending Application No. 10/731,867 (U.S. Publication No. 2004/0176673), and claims 1, 2, and 14–16 of copending Application No. 10/731,868 (U.S. Publication No. 2004/0173221).

Appellant notes that originally-filed claims 2, 12, and 16 of copending Application No. 10/731,699 (U.S. Publication No. 2004/0172090) have been canceled. In addition, originally-filed claims 2, 7, 9, 35, 46, 48, 50, and 52 of copending Application No. 10/730,873 have been canceled. Originally-filed claim 11 of copending Application No. 10/730,878 (U.S. Publication No. 2004/0176816) has also been canceled. In addition, originally-filed claims 2, 11, and 23–27 of copending Application No. 10/731,867 have been canceled.

Appellant filed a Terminal Disclaimer on August 20, 2008. The Terminal Disclaimer obviated the double patenting rejections based on U.S. Patent Nos. 7,212,864 and 7,242,982, and U.S. Patent Application Nos. 10/730,878, 10/731,699, 10/731,867, and 10/731,868.

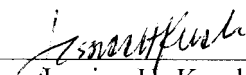
³⁷ Berrang at column 6, lines 12–14

Accordingly, the provisional rejection of claims 1–31 and 33–61 under the judicially created doctrine of obviousness-type double patenting is moot and should be reversed.

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